

FORM PTO-1449/A and B (modified PTO/SB/08)

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

APPLICATION NO.: 09/316,199

ATTY. DOCKET NO.: C1040.70006US00

FILING DATE: May 21, 1999

CONFIRMATION NO.: 7506

APPLICANT: McCluskie et al.

GROUP ART UNIT: 1633

EXAMINER: Quang Nguyen

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of

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**U.S. PATENT DOCUMENTS**

Examiner's Initials #	Cite No.	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication or Issue of Cited Document MM-DD-YYYY
		Number	Kind Code		
		6,221,882	B1	Macfarlane	04-24-2001
		6,399,630	B1	Macfarlane	06-04-2002
		6,479,504	B1	Macfarlane et al.	11-12-2002
		6,521,637	B2	Macfarlane	02-18-2003
		6,943,240	B2	Bauer et al.	09-13-2005
		6,949,520	B1	Hartmann et al.	09-27-2005
		7,001,890	B1	Wagner et al.	02-21-2006
		7,223,741	B2	Krieg	05-29-2007
		2002-0156033	A1	Bratzler et al.	10-24-2002
		2003-0232856	A1	Macfarlane	12-18-2003
		2004-0067902	A9	Bratzler et al.	04-08-2004
		2004-0198680	A1	Krieg	10-07-2004
		2004-0229835	A1	Krieg et al.	11-18-2004
		2004-0234512	A1	Wagner et al.	11-25-2004
		2004-0235770	A1	Davis et al.	11-25-2004
		2004-0235774	A1	Bratzler et al.	11-25-2004
		2004-0235777	A1	Wagner et al.	11-25-2004
		2004-0235778	A1	Wagner et al.	11-25-2004
		2004-0266719	A1	McCluskie et al.	12-30-2004
		2005-0004061	A1	Krieg et al.	01-06-2005
		2005-0004062	A1	Krieg et al.	01-06-2005
		2005-0009774	A1	Krieg et al.	01-13-2005
		2005-0032734	A1	Davis et al.	02-10-2005
		2005-0032736	A1	Krieg et al.	02-10-2005
		2005-0037403	A1	Krieg et al.	02-17-2005
		2005-0037985	A1	Krieg et al.	02-17-2005
		2005-0043529	A1	Davis et al.	02-24-2005
		2005-0049215	A1	Krieg et al.	03-03-2005
		2005-0049216	A1	Krieg et al.	03-03-2005
		2005-0054601	A1	Wagner et al.	03-10-2005
		2005-0054602	A1	Krieg et al.	03-10-2005

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				GROUP ART UNIT: 1633	EXAMINER: Quang Nguyen
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		2005-0059619	A1	Krieg et al.	03-17-2005
		2005-0059625	A1	Krieg et al.	03-17-2005
		2005-0070491	A1	Krieg et al.	03-31-2005
		2005-0075302	A1	Hutcherson et al.	04-07-2005
		2005-0100983	A1	Bauer et al.	05-12-2005
		2005-0101554	A1	Krieg et al.	05-12-2005
		2005-0101557	A1	Krieg et al.	05-12-2005
		2005-0119273	A1	Lipford et al.	06-02-2005
		2005-0123523	A1	Krieg et al.	06-09-2005
		2005-0130911	A1	Uhlmann et al.	06-16-2005
		2005-0148537	A1	Krieg et al.	07-07-2005
		2005-0169888	A1	Hartman et al.	08-04-2005
		2005-0171047	A1	Krieg et al.	08-04-2005
		2005-0181422	A1	Bauer et al.	08-18-2005
		2005-0182017	A1	Krieg	08-18-2005
		2005-0197314	A1	Krieg et al.	09-08-2005
		2005-0215501	A1	Lipford et al.	09-29-2005
		2005-0233995	A1	Krieg et al.	10-20-2005
		2005-0233999	A1	Krieg et al.	10-20-2005
		2005-0239732	A1	Krieg et al.	10-27-2005
		2005-0239733	A1	Jurk et al.	10-27-2005
		2005-0239734	A1	Uhlmann et al.	10-27-2005
		2005-0239736	A1	Krieg et al.	10-27-2005
		2005-0244379	A1	Krieg et al.	11-03-2005
		2005-0244380	A1	Krieg et al.	11-03-2005
		2005-0245477	A1	Krieg et al.	11-03-2005
		2005-0250726	A1	Krieg et al.	11-10-2005
		2005-0256073	A1	Lipford et al.	11-17-2005
		2005-0267064	A1	Krieg et al.	12-01-2005
		2005-0277604	A1	Krieg et al.	12-15-2005
		2005-0277609	A1	Krieg et al.	12-15-2005
		2006-0003955	A1	Krieg et al.	01-05-2006
		2006-0003962	A1	Ahluwalia et al.	01-05-2006
		2006-0019916	A1	Krieg et al.	01-26-2006
		2006-0019923	A1	Davis et al.	01-26-2006

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		2006-0058251	A1	Krieg et al.	03-16-2006
		2006-0089326	A1	Krieg et al.	04-27-2006
		2006-0094683	A1	Krieg et al.	05-04-2006
		2006-0140875	A1	Krieg et al.	06-29-2006
		2006-0154890	A1	Bratzler et al.	07-13-2006
		2006-0172966	A1	Lipford et al.	08-03-2006
		2006-0188913	A1	Krieg et al.	08-24-2006
		2006-0211639	A1	Bratzler et al.	09-21-2006
		2006-0211644	A1	Krieg et al.	09-21-2006
		2006-0229271	A1	Krieg et al.	10-12-2006
		2006-0241076	A1	Uhlmann et al.	10-26-2006
		2006-0246035	A1	Ahluwalia et al.	11-02-2006
		2006-0286070	A1	Hartmann et al.	12-21-2006
		2006-0287263	A1	Davis et al.	12-21-2006
		2007-0009482	A1	Krieg et al.	01-11-2007
		2007-0010470	A1	Krieg et al.	01-11-2007
		2007-0037767	A1	Bratzler et al.	02-15-2007
		2007-0065467	A1	Krieg et al.	03-22-2007
		2007-0066553	A1	Krieg et al.	03-22-2007
		2007-0066554	A1	Krieg et al.	03-22-2007
		2007-0078104	A1	Krieg et al.	04-05-2007
		2007-0129320	A9	Davis et al.	06-07-2007
		2007-0142315	A1	Forsbach et al.	06-21-2007
		2007-0184465	A1	Wagner et al.	08-09-2007
		2007-0202128	A1	Krieg et al.	08-30-2007

#### FOREIGN PATENT DOCUMENTS

Examiner's Initials #	Cite No.	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Translation (Y/N)
		Office/ Country	Number	Kind Code			
		WO	99/56755	A1	University of Iowa Research Foundation	11-11-1999	
		WO	00/06588	A1	University of Iowa Research Foundation	02-10-2000	
		WO	00/14217	A2	CPG Immunopharmaceuticals GMBH	03-16-2000	
		WO	00/67023	A1	CPG Immunopharmaceuticals GMBH	11-09-2000	
		WO	2004/007743	A2	Coley Pharmaceutical GMBH	01-22-2004	

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		WO	2004/026888	A2	Coley Pharmaceutical GMBH	04-01-2004	
		WO	2004/094671	A2	Coley Pharmaceutical GMBH	11-04-2004	
		WO	2006/080946	A2	Coley Pharmaceutical GMBH	08-03-2006	
		WO	2007/031877	A2	Coley Pharmaceutical GMBH	03-22-2007	
		WO	2007/038720	A2	Coley Pharmaceutical GMBH	04-05-2007	

#### OTHER ART — NON PATENT LITERATURE DOCUMENTS

Examiner's Initials #	Cite No	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	Translation (Y/N)
		COOPER et al., CPG 7909, an immunostimulatory TLR9 agonist oligodeoxynucleotide, as adjuvant to Engerix-B HBV vaccine in healthy adults: a double-blind phase I/II study. J Clin Immunol. 2004 Nov;24(6):693-701.	
		DAVIS et al., DNA vaccines for prophylactic or therapeutic immunization against hepatitis B virus. Mt Sinai J Med. 1999 Mar;66(2):84-90.	
		DE LA ROSA et al., Microbiological quality of pharmaceutical raw materials. Pharm Acta Helv. 1995 Sep;70(3):227-32.	
		DIWAN et al., Biodegradable nanoparticle mediated antigen delivery to human cord blood derived dendritic cells for induction of primary T cell responses. J Drug Target. 2003;11(8-10):495-507.	
		GAO et al., Swelling of hydroxypropyl methylcellulose matrix tablets. 2. Mechanistic study of the influence of formulation variables on matrix performance and drug release. J Pharm Sci. 1996 Jul;85(7):732-40.	
		GOMBOTZ et al., Protein release from alginate matrices. Adv Drug Deliv Rev. 1998 May 4;31(3):267-285.	
		HORNER et al., Immunostimulatory DNA is a potent mucosal adjuvant. Cell Immunol. 1998 Nov 25;190(1):77-82.	
		LI et al., Enhanced immune response to T-independent antigen by using CpG oligodeoxynucleotides encapsulated in liposomes. Vaccine. 2001 Oct 12;20(1-2):148-57.	
		LIPFORD et al., CpG-containing synthetic oligonucleotides promote B and cytotoxic T cell responses to protein antigen: a new class of vaccine adjuvants. Eur J Immunol. 1997 Sep;27(9):2340-4.	
		McCLUSKIE et al., CpG DNA is a potent enhancer of systemic and mucosal immune responses against hepatitis B surface antigen with intranasal administration to mice. J Immunol. 1998 Nov 1;161(9):4463-6.	
		MUI et al., Immune stimulation by a CpG-containing oligodeoxynucleotide is enhanced when encapsulated and delivered in lipid particles. J Pharmacol Exp Ther. 2001 Sep;298(3):1185-92.	
		MUTWIRI et al., Strategies for enhancing the immunostimulatory effects of CpG oligodeoxynucleotides. J Control Release. 2004 May 31;97(1):1-17.	
		OXENIUS et al., CpG-containing oligonucleotides are efficient adjuvants for induction of protective antiviral immune responses with T-cell peptide vaccines. J Virol. 1999 May;73(5):4120-6.	

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-----------	------------------

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				GROUP ART UNIT: 1633	EXAMINER: Quang Nguyen
Sheet	5	of	5		

	SCHIJNS. Immunological concepts of vaccine adjuvant activity. Curr Opin Immunol. 2000 Aug;12(4):456-63.	
	SEMPLE et al., Immunogenicity and rapid blood clearance of liposomes containing polyethylene glycol-lipid conjugates and nucleic Acid. J Pharmacol Exp Ther. 2005 Mar;312(3):1020-6.	
	SHAO et al., CpG-containing oligodeoxynucleotide 1826 converts the weak uveitogenic rat interphotoreceptor retinoid-binding protein peptide 1181-1191 into a strong uveitogen. J Immunol. 2003 Nov 1;171(9):4780-5.	
	SUZUKI et al., Liposome-encapsulated CpG oligodeoxynucleotides as a potent adjuvant for inducing type 1 innate immunity. Cancer Res. 2004 Dec 1;64(23):8754-60.	
	TAFAGHODI et al., Induction of systemic and mucosal immune responses by intranasal administration of alginate microspheres encapsulated with tetanus toxoid and CpG-ODN. Int J Pharm. 2006 Aug 17;319(1-2):37-43.	
	TAM et al., Liposomal encapsulation enhances the activity of immunostimulatory oligonucleotides. Future Lipidology. 2006 Feb; 1(1): 35-46	
	UGOZZOLI et al., Intranasal immunization of mice with herpes simplex virus type 2 recombinant gD2: the effect of adjuvants on mucosal and serum antibody responses. Immunology. 1998 Apr;93(4):563-71.	
	VON HUNOLSTEIN et al., Synthetic oligodeoxynucleotide containing CpG motif induces an anti-polysaccharide type 1-like immune response after immunization of mice with Haemophilus influenzae type b conjugate vaccine. Int Immunol. 2000 Mar;12(3):295-303.	
	VON HUNOLSTEIN et al., The adjuvant effect of synthetic oligodeoxynucleotide containing CpG motif converts the anti-Haemophilus influenzae type b glycoconjugates into efficient anti-polysaccharide and anti-carrier polyvalent vaccines. Vaccine. 2001 Apr 30;19(23-24):3058-66.	
	WANG et al., Synergy between CpG- or non-CpG DNA and specific antigen for B cell activation. Int Immunol. 2003 Feb;15(2):223-31.	
	WEERATNA et al., TLR agonists as vaccine adjuvants: comparison of CpG ODN and Resiquimod (R-848). Vaccine. 2005 Nov 1;23(45):5263-70.	

\*a copy of this reference is not provided as it was previously cited by or submitted to the office in a prior application, Serial No. \_\_, filed \_\_, and relied upon for an earlier filing date under 35 U.S.C. 120 (continuation, continuation-in-part, and divisional applications).

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